S.N. 303,747
Part #8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mostafa S. Fahim
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Group Art Unit 125
Examiner: R. Henley III

DECLARATION UNDER RULE 132

The Commissioner of Patents and Trademarks
Washington, D. C. 20231

Dear Sir:

I, Mostafa S. Fahim, declare and say that I conducted the following studies:

Example 1

The stability of a first solution of 0.05 M (2.549%) zinc gluconate neutralized with 0.05 M (1.742%) arginine to pH 7.0 was observed for 18 months under the following conditions:

1. Refrigerator
2. Freezer
   On a monthly basis, samples were thawed to note any precipitation then refrozen.
3. Maintained at 40° C
4. Maintained at 60° C
5. Room temperature
6. Exposed to sun for one week during the month of July
7. Exposed for 10 minutes to 250 watt infrared lamp
8. Exposed for 10 minutes to 275 watt ultra-violet lamp

During the test, the solution was placed in ten 30 ml clear glass flasks and sealed. No precipitation or cloudiness occurred in the zinc + amino acid solution prepared on a molar weight ratio of 1:1.

No precipitation was observed with a second solution of 0.05 M (2.549%) zinc gluconate neutralized with 0.05 M (0.731%) lysine to pH 7.0, also having a zinc + amino acid molar weight ratio of 1:1.

Example 2

The following solutions prepared on a zinc + amino acid molar ratio of 1:2 and neutralized to pH 7.0 were placed in ten glass flasks, five made of clear glass and five made of amber glass. Both solutions precipitated in a short period of time as reported in the following tables.

Table 1

Molar ratio:	Zn Gluconate	+	Arginine
1:2	0.05 Molar		0.1 Molar
Concentration %	2.549%		0.871%

STABILITY TIME

Solution Precipitation	Clear glass* hour/minutes	Amber glass* hour/minutes
1	4.10	7.12
2	3.50	8.20
3	4.15	8.15
4	4.00	9.00
5	4.00	7.00
$\bar{x}$	3.95	7.89
S.D.	0.26	0.87
S.E.	0.12	0.37

*30 ml size of clear and amber glass

Table 2

Molar ratio:	Zn Gluconate	+	Lysine
1:2	0.05 Molar		0.1 Molar
Concentration %	2.549%		1.462%

PRECIPITATION TIME AFTER MIXING

Solution Precipitation	Clear glass* hour/minutes	Amber glass* hour/minutes
1	2.28	3.40
2	3.40	2.10
3	4.10	3.35
4	2.58	4.02
5	3.17	3.29
$\bar{x}$	3.11	3.23
S.D.	0.71	0.70
S.E.	0.32	0.31

*30 ml size of clear and amber glass

Example 3

A sexually mature male dog was injected into each testis with 4.0 ml of a solution of 0.2 M zinc gluconate neutralized with 0.2 M arginine to pH 7.0. The animal tolerated the injections without incident. The zinc + amino acid molar weight ratio was 1:1.

When a second sexually mature male dog was injected into each testis with 4.0 ml of a solution of 0.2 M zinc gluconate neutralized with 0.4 M arginine to pH 7.0, the testes ruptured. The zinc + amino acid molar weight ratio was 1:2.

Example 4

Five dogs were fed daily 5 ml of a solution of 0.05 M (2.549%) zinc gluconate neutralized with 0.05 M (1.742%) arginine to pH 7.0 for two months with no adverse side effects. However, when five doges were fed daily 5 ml of a solution of 0.05 M (2.549%) zinc gluconate neutralized with 0.1 M (3.48%) arginine, three of the animals began to vomit within 24 hours and the experiment had to be discontinued after 3 days because of animal distress. The zinc + amino acid molar weight ratio was 1:1 in the first feeding study and 1:2 in the second.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 12 - 17 - 87

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